

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/640,738 05/06/96 HYON

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EXAMINER

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ART UNIT	PAPER NUMBER
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3738

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DATE MAILED:

01/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/640,738

Applicant(s)

Hyon et al.

Examiner

Tram Nguyen

Group Art Unit

3738

 Responsive to communication(s) filed on Nov 9, 1999 This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims Claim(s) 1, 3, and 5-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

 Claim(s) _____ is/are allowed. Claim(s) 1, 3, and 5-13 is/are rejected. Claim(s) _____ is/are objected to. Claims _____ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on _____ is/are objected to by the Examiner. The proposed drawing correction, filed on _____ is approved disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). 21, 25 Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Continued Prosecution Application

1. The request filed on Nov. 9, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/640,738 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons:

Regarding claims 10 and 11, applicant recites that the artificial joint for implantation comprises a molded block of slightly crosslinked ultra high molecular weight polyethylene, which renders the claim indefinite insofar as applicant has recited that the implanted article is one which is different from that disclosed in the specification. That is, applicant has claimed that the artificial joint comprises an intermediate product (i.e., the slightly crosslinked raw material of ultra high molecular weight polyethylene) but the specification teaches that the artificial joint is actually comprised of a final product which is "cut" from the intermediate product, the molded block (see applicant's specification, page 8, lines 23-32). Therefore, applicant's recitation that a molded block is actually implanted into the animal or patient is indefinite insofar as the examiner cannot

find in the specification where applicant discloses that the molded block (i.e., the raw material which has been slightly crosslinked but not "cut") is implanted into the patient. As understood by the examiner, the artificial joint of the instant invention comprises more than just the molded block but a shaped or "cut" molded block which has the structural attributes which make it suitable for implantation inside a patient's joint.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. '696 in view of Kitamaru et al. '056, for the following reasons:

With respect to claims 1, 3, 5, and 9-13, Murray et al. discloses in col. 6, lines 19-25 and 37-44 an artificial joint (i.e., meniscal plate) for implantation in a knee joint of an animal comprising an ultra high molecular weight polyethylene molded block, the block having a thickness range of over 5 mm. However, Murray et al. fails to disclose that the molded block is slightly crosslinked and compression-deformed so as to have an orientation of crystal planes in a direction parallel to the compression plane. Kitamaru et al. teaches in col. 1, lines 65-68, col. 2, lines 1-44, and col. 4, lines 58-65 a method of producing a high melting temperature ultra high molecular weight polyethylene molded article which has excellent dimensional stability at high

temperatures due to its high crystallinity (see esp. col. 1, lines 1-35), the molded article being partially crosslinked by irradiation and being compression-deformed in a direction perpendicular to a compression plane, the article having orientation of crystal planes in a direction parallel to the compression plane, the article having a melting temperature of 137°-138°C. Since the stock material of Murray et al. is identical to that of Kitamaru et al. (in the sense that both teach articles formed from ultra high molecular weight polyethylene), it would have been obvious to one of ordinary skill in the art at the time of the invention to have substituted the slightly crosslinked ultra high molecular weight polyethylene of Kitamaru et al. for the non-crosslinked ultra high molecular weight polyethylene of Murray et al., in order to provide a molded article for an artificial joint which has high crystallinity and enhanced dimensional stability, as taught by Kitamaru et al., and further since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

- b. With respect to claims 6 and 7, see Kitamaru et al., col. 3, lines 1-20 for the recited irradiation dose and compression-deformation temperature.
- c. With respect to claim 8, see Kitamaru et al., col. 2, lines 38-44 for the recited weight-average molecular weight.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 3, and 5-13 have been considered but are moot in view of the new ground(s) of rejection. Applicant is asked to please refer to the modified

prior art rejection above wherein examiner addresses applicant's specific concerns regarding prior art rejections, as well as examiner's response below.

With regard to applicant's recitation of a "block" having the dimensions now claimed, applicant is asked to please refer to the above modified prior art rejection wherein the examiner addresses this issue. Furthermore, the examiner wishes to point out that the structural limitations which are newly recited would not overcome an obviousness rejection over Kitamaru et al. alone. With regard to the method of making the molded article, while Kitamaru et al. does not disclose the particular dimensions recited, it would have been obvious to have modified the method of Kitamaru et al. to produce a larger molded block, if the ultimate use of the molded block is to form a product which requires that particular dimension. That is, such a modification to alter the size of the product of Kitamaru et al. would have been obvious to one of ordinary skill in the art at the time of the invention if the desired result is a molded ultra high molecular weight polyethylene article having a thickness of greater than 5 mm (so that you could cut the block to form, for example, a meniscal plate). Thus, depending on the intended use of the block of material, you would adjust the size of the intermediate product to allow for enough material to form the final product.

With regard to applicant's argument that the "stretching" step of Kitamaru et al. is not analogous to a "compression" step, the examiner respectfully disagrees. As noted both during the interview and in the previous office action, Kitamaru et al. teaches stretching the molded article through the use of a rolling apparatus. The examiner believes that when the larger, more irregularly shaped molded article is fed through the rolling apparatus to achieve the dimensionally

smaller, and more uniformly shaped molded article, there is an inherent compression step being performed as the irregularly shaped molded article passes through the rollers and is "pressed" to a more uniform (i.e., flat, or planar) shape. Hence, the examiner maintains that Kitamaru et al. meets the limitations of the claimed invention.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Davidson '529 also shows an artificial joint formed from ultra high molecular weight polyethylene having the recited dimensions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tram Nguyen whose telephone number is (703) 308-0804. The examiner can normally be reached on Monday - Friday from 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached at (703) 308-2672. The fax phone number for this group is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceedings should be directed to the group receptionist whose telephone number is (703) 308-0858.


MICHAEL J. MILANO
PRIMARY EXAMINER
GROUP 3700

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December 27, 1999